U.S. FOOD & DRUG ADMINISTRATION

October 24, 2023

Vein 360 LLC
Suzanne Meyer, CEO
4460 Lake Forest Dr Suite 230
Blue Ash, Ohio 45242-3741

Re: K232584
Trade/Device Name: Vein360 Reprocessed Visions PV.014P RX Digital IVUS Catheter (85910P), Vein360 Reprocessed Visions PV.014P RX Digital IVUS Catheter (014R), Vein360 Reprocessed Eagle Eye Platinum RX Digital IVUS Catheter, Vein360 Reprocessed Eagle Eye Platinum ST RX Digital IVUS Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: Class II
Product Code: OWQ
Dated: August 23, 2023
Received: August 25, 2023

Dear Suzanne Meyer:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Aneesh S. Deoras -S

Aneesh Deoras
Assistant Director
Division of Cardiac Electrophysiology,

Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

The item numbers included in the scope of this submission are as follows:

Subject Device Trade Name	Reference Number	**French Size**	**Guide Wire**	Minimum Sheath	**Working Length**
Vein360 Reprocessed Visions PV.014P RX Digital IVUS Catheter	VEN-PV-014P	3.5F	0.014"	5F	150 cm
Vein360 Reprocessed Eagle Eye Platinum RX Digital IVUS Catheter	VEN-PV-EEP	3.5F	0.014"	5F	150 cm
Vein360 Reprocessed Eagle Eye Platinum ST RX Digital IVUS Catheter	VEN-PV-EEPST	3.5F	0.014"	5F	150 cm
Vein360 Reprocessed Visions PV.014P RX Digital IVUS Catheter	VEN-PV-014R	3.5F	0.014"	5F	150 cm

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K232584

Device Name
Vein360 Reprocessed Visions PV.014P RX Digital IVUS Catheter (85910P), Vein360 Reprocessed Visions PV.014P RX Digital IVUS Catheter (014R), Vein360 Reprocessed Eagle Eye Platinum RX Digital IVUS Catheter, Vein360 Reprocessed Eagle Eye Platinum ST RX Digital IVUS Catheter

Indications for Use *(Describe)*
The Vein360 Reprocessed Visions® PV .014P RX (85910P), Visions® PV.014P RX (014R), Eagle Eye Platinum RX, and Eagle Eye Platinum ST RX Digital IVUS catheters are all designed for use in the evaluation of vascular morphology in blood vessels of the coronary and peripheral vasculature by providing a cross-sectional image of such vessels. These devices are not currently indicated for use in the cerebral vessels.

The Vein360 Reprocessed Visions® PV .014P RX (85910P), Visions® PV.014p RX (014R), Eagle Eye Platinum RX, and Eagle Eye Platinum ST RX Digital IVUS catheters are designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures.

Type of Use *(Select one or both, as applicable)*

X Prescription Use (Part 21 CFR 801 Subpart D) Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY K232584

VEIN (4)0

Date of Preparation: August 23rd, 2023

Company Name / Contact:

Company: Vein360, LLC
4460 Lake Forest Drive
Suite 230
Blue Ash, OH 45242

Contact: Suzanne Meyer
CEO
Phone: (513) 554-1300

Device Identification:

Proprietary Names:	Vein360 Reprocessed Visions PV.014P RX Digital IVUS Catheter (85910P) Vein360 Reprocessed Eagle Eye Platinum RX Digital IVUS Catheter Vein360 Reprocessed Eagle Eye Platinum ST RX Digital IVUS Catheter Vein360 Reprocessed Visions PV.014P RX Digital IVUS Catheter (014R)
Common Name:	Diagnostic Intravascular Catheter
Classification Reference:	21 CFR 870.1200
Classification Panel:	Cardiovascular
Device Product Code:	OWQ
Regulatory Class:	Class II

Predicate Devices:

The primary predicate device for this submission is K143701. The secondary predicate device for this submission is K152829.

Device Description:

The subject devices are reprocessed single use devices. After clinical use of the predicate devices (Manufactured by Philips), the devices are shipped to Vein360 per established Vein360 instructions. Upon receipt, the subject devices are cleaned, inspected, hydrophilic coated, functionally tested, packaged, and sterilized using ethylene oxide (EO) gas.

The subject devices are rapid exchange intravascular imaging catheters containing an ultrasound transducer located at the distal end of the catheter. This transducer utilizes a 64-element cylindrical array that radiates acoustic energy into the surrounding tissue and detects subsequent echoes. The information from the echoes is used to generate real-time images of the coronary and peripheral vessels.

The subject devices utilize an internal lumen that allows the catheter to track over the 0.014" (0.36mm) guide wire. The guide wire exits from the guide wire lumen approximately 24 cm proximal to the catheter tip. The subject devices are introduced percutaneously or via surgical cutdown into the vascular system.

Three 1 mm-long radiopaque markers are incorporated on the internal lumen positioned 10 mm apart from distal edge to distal edge, starting 10 mm from the proximal edge of the portion of the scanner marker tube normally visible under fluoroscopy.

The subject devices may only be used with Volcano s5 Series or CORE Series imaging systems.

The subject device is packaged with a flushing tool that is equivalent to the predicate and is used for flushing the device's lumen with heparinized normal saline.

The subject devices are reprocessed once and permanently marked to indicate it has been reprocessed by Vein360.

The scope of this submission is as follows:

Subject Device Trade Name	Reference Number	French Size	Guide Wire	Minimum Sheath	Working Length
Vein360 Reprocessed Visions PV.014P RX Digital IVUS Catheter (85910P)	VEN-PV-014P	3.5F	0.014"	5F	150 cm
Vein360 Reprocessed Eagle Eye Platinum RX Digital IVUS Catheter	VEN-PV-EEP	3.5F	0.014"	5F	150 cm
Vein360 Reprocessed Eagle Eye Platinum ST RX Digital IVUS Catheter	VEN-PV-EEPST	3.5F	0.014"	5F	150 cm
Vein360 Reprocessed Visions PV.014P RX Digital IVUS Catheter (014R)	VEN-PV-014R	3.5F	0.014"	5F	150 cm

Indications for Use:

The Vein360 Reprocessed Visions® PV .014P RX (85910P), Visions® PV.014P RX (014R), Eagle Eye Platinum RX, and Eagle Eye Platinum ST RX Digital IVUS catheters are all designed for use in the evaluation of vascular morphology in blood vessels of the coronary and peripheral vasculature by

providing a cross-sectional image of such vessels. These devices are not currently indicated for use in the cerebral vessels.

The Vein360 Reprocessed Visions® PV .014P RX (85910P), Visions® PV.014p RX (014R), Eagle Eye Platinum RX, and Eagle Eye Platinum ST RX Digital IVUS catheters are designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures.

Substantial Equivalence Information:
The subject devices are substantially equivalent to the predicate devices of the same product currently marketed by the device's original equipment manufacturer (OEM) and described herein with respect to intended use, design, materials, performance, and function. As a reprocessed single use device (SUD), there are no changes to the clinical applications, patient population, or method of operation. A high-level comparison of features between the predicate and subject devices is provided below.

Feature	Predicate Device (K143701, K152829)	Subject Device
Hydrophilic Coating Length	24cm	Identical
Working Length	150cm	Identical
Max Working Length Diameter	3.3 F	Identical
Transducer Diameter	3.5 F	Identical
Guidewire Compatibility	0.014" (0.36mm)	Identical
Sterilization Method	Ethylene Oxide (EO) gas	Identical
Markers	3 radiopaque markers	Identical
Shelf Life	2 years	13 months
Uses	Single patient use	Identical
Accessories	Flushing tool	Equivalent

Performance Data:
With respect to SUD reprocessing, comprehensive cleaning validation studies were performed ensuring subject devices were clinically used and then soiled with artificial test soil. The cleaning operation was validated with a high degree of confidence by objectively demonstrating removal of all physical soil under minimum operating conditions. The body of this submission includes all data related to the cleaning process and validation.

Performance validation studies were performed after ensuring subject devices were clinically used and then soiled with artificial test soils. The cleaning process was conducted using maximum operating conditions to challenge functional performance of the device. Electro-mechanical performance testing was performed

to demonstrate that the reprocessing operations did not adversely affect the predicate device's form, fit, or function.

Results of performance testing demonstrate the subject devices are substantially equivalent to the predicate devices which are safe and effective for their intended use. Substantial equivalence determination was concluded through successful completion of bench and laboratory testing, which included:

Cleaning Validation
Drying Validation
Sterilization Validation
Endotoxin Test Method Validation
Biocompatibility
Performance Validation
- Simulated Use
- Dimensional Integrity
- Mechanical integrity
- Cross / re-cross Testing
- Electrical Integrity
- Electrical Safety
- Hydrophilic Coating Integrity
- Acoustic Output
- Image Quality
- System Compatibility

Packaging Validation

The subject devices are validated for one reprocessing cycle after successful completion of the above performance testing. All subject devices are permanently marked and are tracked via OEM label during reprocessing. Subject devices are taken out of service and rejected from further reprocessing once the maximum number of cycles have been reached. Further, Vein360 restricts its reprocessing to exclude devices previously reprocessed by other reprocessors.

Conclusion:
Vein360 concludes the subject devices are as safe, as effective, and perform as well as or better than the predicate devices.